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(71) Applicant *(for all designated States except US)*: **NOVO NORDISK A/S** [DK/DK]; Novo Allé, DK-2880 Bagsværd (DK).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BITSCH, Lennart** [DK/DK]; Provstevej 3a, DK-3400 Hillerød (DK). **LARSEN, Torben, Storgaard** [DK/DK]; Ny Strandvej 147, DK-3050 Humlebæk (DK). **NIELSEN, Ole, Christian** [DK/DK]; Hestehavevej 22, DK-3400 Hillerød (DK).

(74) Common Representative: **NOVO NORDISK A/S**; Corporate Patents, Novo Allé, DK-2880 Bagsværd (DK).

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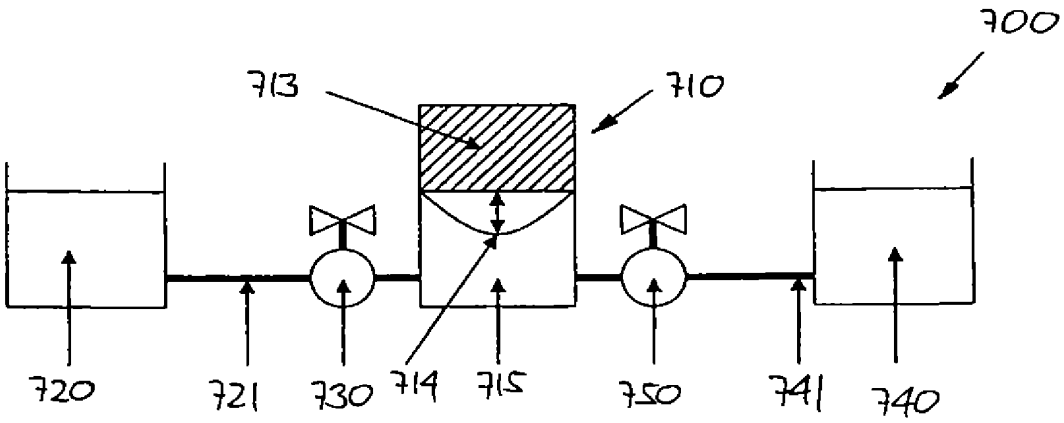
(54) Title: PUMP ASSEMBLY WITH ACTIVE AND PASSIVE VALVE



(57) Abstract: The present invention generally relates to a pump assembly comprising a valve arrangement adapted to prevent unintended flow of fluid through the pump assembly. The invention pro- vides a pump assembly, comprising a displacement pump, an inlet valve allowing a flow of 5 fluid into the displacement pump, and an outlet valve allowing a flow of fluid from the displacement pump. Either the inlet or the outlet valve is a passive valve controlled by a pres- sure differential across the valve generated by the displacement pump, and the other of the inlet and the outlet valve is an active valve controllable by an actuator. By replacing a tradi- tional passive valve a more compact and cost-effective design can be achieved when com- 10 pared to a design wherein a safety valve was added as a further valve, just as the energy loss across one traditional passive valve can be eliminated.

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PUMP ASSEMBLY WITH ACTIVE AND PASSIVE VALVE

The present invention generally relates to a pump assembly comprising a valve arrangement adapted to prevent unintended flow of fluid through the pump assembly. In a specific aspect, the invention relates to improvements in safety design for a pump assembly suitable to be used in a drug infusion device, the safety design being provided in order to avoid overdoses resulting from, e.g., an excessive external pressure to a drug reservoir.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by injection or infusion of insulin, however, this is only an exemplary use of the present invention.

Portable drug delivery devices for delivering a drug to a patient are well known and generally comprise a reservoir adapted to contain a liquid drug and having an outlet in fluid communication with a hollow infusion needle, as well as expelling means for expelling a drug out of the reservoir and through the skin of the subject via the hollow needle. Such devices are often termed infusion pumps.

Basically, infusion pumps can be divided into two classes. The first class comprises infusion pumps which are relatively expensive pumps intended for 3-4 years use, for which reason the initial cost for such a pump often is a barrier to this type of therapy. Although more complex than traditional syringes and pens, the pump offer the advantages of continuous infusion of insulin, precision in dosing and optionally programmable delivery profiles and user actuated bolus infusions in connections with meals.

Addressing the above cost issue, several attempts have been made to provide a second class of drug infusion devices that are low in cost yet convenient to use. Some of these devices are intended to be partially or entirely disposable and may provide many of the advantages associated with an infusion pump without the attendant cost and inconveniencies, e.g. a disposable pump may be prefilled thus avoiding the need for filling or refilling a drug reservoir. Examples of this type of infusion devices are known from US patents 4,340,048 and 4,552,561 (based on osmotic pumps), US patent 5,858,001 (based on a piston pump), US patent 6,280,148 (based on a membrane pump), US patent 5,957,895 (based on a flow re-

strictor pump), US patent 5,527,288 (based on a gas generating pump), or US patent 5,814,020 (based on a swellable gel) which all in the last decades have been proposed for use in inexpensive, primarily disposable drug infusion devices, the cited documents being incorporated by reference. The disposable infusion devices generally comprises a mounting surface adapted for application to the skin of a subject by adhesive means, and a transcutaneous device adapted to be inserted through the skin of the subject, e.g. a needle or a soft cannula. The needle or the soft cannula may be insertable after the device has been arranged on the skin.

The drug reservoirs used for such infusion devices may be in the form of a "hard" reservoir (e.g. a cylinder-piston reservoir) or a flexible reservoir. The "hard" reservoir provides inherently good protection against accidental compression of the reservoir from the outside, thereby reducing the risk of unintended expelling of drug from the infusion device and into the patient when subjected to excessive forces, e.g. the patient carrying a skin-mounted infusion device may stumble or walk into a hard object, or the infusion device may be hit by an object. However, when a flexible reservoir is compressed from the outside the contained drug may be expelled through the outlet and into the patient. Although such a flexible reservoir normally will be protected by a relatively rigid housing, the housing may brake when subjected to excessive force, this allowing the flexible reservoir to be compressed and drug thereby unintentionally infused into the patient. Depending on the construction of the infusion device, a flexible reservoir may be arranged "downstream" of the expelling means, e.g. as for a gas generating pump, or "upstream" of the expelling means, e.g. as for a suction pump.

As an example, membrane pumps constitute suitable pump engines for small and precise dosing. Spencer et al. [Ref. 1] have proposed a piezoelectric pump with electronically controlled valves for insulin dosing. In this device, high voltages are used for actuation, and the actuators are immersed into the pumped fluid, which is a potential hazard. This problem was addressed by Smits [Ref. 2], who suggests a membrane pump operated in a peristaltic way, wherein the actuators are clearly separated from the pumped fluid. However, this device also relies on high actuation voltage. There is also a risk for free fluid flow in the device as a result of an external pressure on e.g. a fluid reservoir, i.e. as a result of a large pressure drop across the valves. Another trend in the prior art is the use of a single actuated pump membrane, wherein check valves guide the fluid flow. To avoid free flow of liquid, a separate valve is added downstream of an outlet check valve. This valve, which comprises a thin elastic wall, is connected to the inlet channel, and is therefore forced to close, when the inlet

pressure increases. Although promising, there may be concerns that the thin elastic wall separating the inlet and outlet channel breaks or is damaged, which would impair the performance of the device. A different approach has been to pre-stress the inlet valve to achieve an opening pressure of 100 mbar [Ref. 4]. However, when the opening pressure is exceeded, the fluid can flow freely, thus jeopardizing security. Furthermore, unnecessary pumping energy is lost in the process of deflecting the check valves.

Having regard to the above-identified problems, it is an object of the present invention to provide a pump assembly comprising a valve design adapted to prevent unintended flow of fluid through the pump assembly. The pump assembly design should be compact, yet allowing for cost-effective manufacturing. It is a further object to provide a medical infusion device comprising a flexible reservoir and providing a high degree of safety of use.

SUMMARY OF THE INVENTION

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

Thus, in a first aspect a pump assembly is provided comprising a displacement pump, an inlet valve allowing a flow of fluid into the displacement pump, an outlet valve allowing a flow of fluid from the displacement pump, wherein either the inlet or the outlet valve is a passive valve controlled by a pressure differential across the valve generated by the displacement pump, and the other of the inlet and the outlet valve is an active valve controllable by an actuator. A passive valve is often termed a check valve, such a valve being open for a flow of fluid in one direction, and closed for a flow of fluid in the opposite direction, i.e. a unidirectional valve. By the term passive is understood that opening and closing of the valve is controlled by a pressure differential across the valve in the fluid flowing through the valve, i.e. located on each side of the valve. By the term active is understood that the valve is activated, e.g. energized, by other means than from a pressure differential across the valve. The active valve of the invention serves as a functional and essential part of the pump mechanism, i.e. as one of the flow control valves allowing the displacement pump to operate properly, and is not merely a safety valve but replaces a passive check valve. Typically, an active valve is actuated by physically moving a valve member. In the context of the present disclosure, the

term displacement pump is used to denote the displacing entity *per se*, and does thus not define a fully working pump, e.g. including inlet and outlet valves.

As appears, by the provision of an active valve, it will be possible to positively control the flow of fluid through the pump assembly and thus to prevent an unintended flow of fluid, the active valve thereby functioning as a safety valve. Further, by replacing a traditional passive valve a more compact and cost-effective design can be achieved when compared to a design wherein a safety valve was added as a further valve, just as the energy loss across one traditional passive valve can be eliminated.

The active valve may be activated by an energy source other than the pressure of the fluid, and which is controllable by a control signal. The control signal may be activated independently from the pressure in the flow conduit or in dependence thereof, e.g. in a sequential manner. For example, the control signal for closing the active valve may be generated in response to a signal produced by a pressure sensor when the pressure in, e.g., a flow conduit exceeds a predetermined threshold value. The active valve may alternatively be activated by a pump actuator, i.e. an actuator which generates a control signal for the active valve to close when the pressure in the pump chamber exceeds a predetermined threshold value. The active valve included in the pump assembly of the present invention is arranged such that it may be opened and closed by a force component, which is transverse to the direction of fluid, and which acts on a valve shutter. For example, the safety valve may be a sliding valve, in which a gate is arranged to slide transversely to the flow direction, or a ball (or rod) valve which has a through-going bore, whereby in an open state of the valve, the bore defines a flow passage through the valve, whereas in a closed state, the bore is essentially perpendicular to the flow conduit, so that the ball blocks the passage of liquid flow in the flow conduit. Such valves are characterised by their ability to, once closed, remain in their closed state irrespective of the pressure of liquid up- or downstream of the valves. In order to ensure reliability and low power consumption of the valve, the pressure in the fluid should preferably not have a pressure component acting in the direction of opening/closure of the shutter of the valve. In other words, the active valve is preferably arranged in the flow conduit in such a way that the pressure in the flow conduit cannot open the active valve once shut, unless the pressure upstream of the valve rises to a level, at which the valve is mechanically broken. Additional examples of suitable valves is given in the below detailed description of the invention.

It will be appreciated that a high security level in e.g. a drug infusion device, i.e. a level of security preventing non-desired opening of a valve even in case of extremely high pressures upstream of the valve, would require a heavily pre-stressed check valve resulting in relatively high losses in the system, as the displacement pump would have to produce a pressure large enough to overcome the backpressure defined by the check valve. A safety valve may also be provided in the form of e.g. a scuba-type valve opened by pressure generated by the pump, however, such an actuation would also consume energy. The present inventors have realised that overall power consumption can be reduced by replacing a traditional check valve by an active valve, though the active valve itself consumes power, such reduction in power consumption being particularly achievable in respect of systems with a high security level, as such systems would require heavily pre-stressed check-valves if no active valve was included. This is due to the fact that the pump consumes less power when it does not have to overcome a backpressure of a heavily pre-stressed check valve. This also applies if a further (i.e. in addition to the in- and outlet valves) pump-actuated safety valve is provided.

The active valve may be closed when not actuated, i.e. being biased towards its closed position, or the active valve may be adapted to be positioned in either a closed or open position.

The active valve may be activated by fluid pressure generated by the displacement pump, either directly, or the fluid pressure from the pump to the active valve may be controllable by an actuator, i.e. the pump would serve as a servomotor to open the valve.

In an exemplary embodiment the pump assembly further comprises a controller, a pump actuator for actuating the displacement pump, and a valve actuator, wherein the controller is adapted to actuate the pump actuator respectively the valve actuator to provide a flow of fluid through the displacement pump.

The pump assembly may be provided with an inlet conduit associated with the inlet valve and an outlet conduit associated with the outlet valve, and may further comprise detecting means for detecting an elevated pressure condition in the inlet or a decreased pressure in the outlet conduit, wherein the controller is adapted to close the active valve in response to the detection of the elevated or decreased pressure. In this way it can be prevented that fluid is forced or sucked through the pump during a normal actuation cycle of the pump and valves in which the active is open.

In a further exemplary embodiment the pump assembly comprises a flexible reservoir containing a fluid drug in an interior thereof, the reservoir being in fluid communication with or adapted to be arranged in fluid communication with the inlet valve. A transcutaneous device adapted to be inserted through the skin of a subject may be provided, the transcutaneous device being arranged or adapted to be arranged in fluid communication with the outlet valve.

The invention further provides a medical assembly comprising a pump assembly as disclosed above, further comprising a transcutaneous device unit, the latter comprising a transcutaneous device adapted to be inserted through the skin of a subject, a mounting surface adapted for application to the skin of a subject, wherein the transcutaneous device unit and the pump assembly are adapted to be mounted to each other in a situation of use, and the transcutaneous device is adapted to be arranged in fluid communication with the outlet valve.

In a further aspect a method for operating a pump assembly is provided, the pump assembly comprising a displacement pump, an active inlet valve allowing a flow of fluid into the displacement pump, the active valve being controllable by external means between a closed and an open state, and a passive outlet valve allowing a flow of fluid from the displacement pump. The method comprises the steps of: (a) opening the active valve, (b) activating the displacement pump to perform a suction stroke, (c) closing the active valve, and (d) activating the displacement pump to perform an expelling stroke, the displacement pump thereby creating a pressure differential across the passive outlet valve, thereby opening the outlet valve. Depending on the actual design of the pump assembly, the displacement pump may be at least partially activated before the active valve is opened.

Alternatively, a method for operating a pump assembly is provided, the pump assembly comprising a displacement pump, a passive inlet valve allowing a flow of fluid into the displacement pump, and an active outlet valve allowing a flow of fluid from the displacement pump, the active valve being controllable by external means between a closed and an open state. The method comprises the steps of (a) activating the displacement pump to perform a suction stroke, the displacement pump thereby creating a pressure differential across the passive inlet valve, thereby opening the inlet valve, (b) opening the active valve, (c) activating the displacement pump to perform an expelling stroke, and (d) closing the active valve.

In summary, the present invention provides a power-efficient and safe pump assembly suitable for use in a drug infusion system. In the present context, the term "displacement pump", in literature also referred to as "positive displacement pump", should be understood as any pump, which includes movable means for generating a pressure gradient in the device, for example a reciprocating pump including a piston, plunger or diaphragm for displacing the liquid drug, or a rotary pump including one or more rotating impellers inside a stationary housing for displacing the liquid drug.

In a further aspect of the present invention, a self-sealing valve is provided, comprising an inlet and an outlet, a valve body comprising a flexible, incompressible material, a valve member comprising a through-going opening and being moveable between an open position in which a flow pathway is provided between the inlet and the outlet, and a closed position in which the flow pathway between the inlet and the outlet is blocked, a seal being formed between the valve member and the flexible, incompressible material, wherein in a closed position of the valve a pressure increase on either the inlet or outlet side of the valve member displaces incompressible material on the pressurized side of the valve member to an opposed side of the valve member, thereby creating a pressure seal between the valve member and the displaced material.

The valve member may e.g. be in the form of a rod rotatably arranged in the valve body. At least a portion of the flexible, incompressible material may be enclosed within a surrounding rigid housing to thereby ensure that the incompressible material effectively is displaced from the pressurized side of the valve to the opposed side.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a hollow needle in a controlled manner, such as a liquid, solution, gel or fine suspension. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin. Correspondingly, the term "subcutaneous" infusion is meant to encompass any method of transcutaneous delivery to a subject.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with reference to the drawings, wherein

Fig. 1 is a schematic representation of an embodiment of a drug infusion system,

Fig. 2 is a schematic representation of a further embodiment of a drug infusion system,

Figs. 3A-3C show in schematic representations actuation and control means for an active valve in a system of the type shown in fig. 2,

Figs. 4-6 show different designs for an active micro valve,

Figs. 7-9 show in perspective views sequences of use for a first embodiment of a drug delivery device,

Fig. 10 shows a pump unit with an upper portion of the housing removed,

Figs. 11A and 11B show in a non-assembled respectively assembled state a cannula unit and a reservoir unit for a further embodiment of a drug delivery device, and

Figs. 12A and 12B show a valve with self-sealing capability due to use of an incompressible material.

In the figures like structures are identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

The shown figures are schematic representations for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

Fig. 1 is a schematic representation of an embodiment of a drug infusion system 600 comprising an additional valve serving as a safety valve. Upstream of the pump 610 the device comprises a drug reservoir 620, an inlet flow conduit 621 with an inlet valve 630. The pump includes a movable portion 614, a pump chamber 615 and an actuator 613 for reciprocating the movable portion. Downstream of the pump the device comprises an outlet reservoir 640,

an outlet flow conduit 641 with an outlet valve 630 and an active safety valve 670. The safety valve may also be arranged on the inlet side. The outlet reservoir is disclosed in place of a patient. The inlet and outlet valves and are passive check valves and are included to direct the flow, i.e. to ensure that drug is sucked from the inlet conduit when the pump chamber is being filled and that drug is expelled into the outlet conduit when the pump chamber is being emptied. If no safety valve was provided, it would be possible to either force fluid through the pump and past the two passive check valves from the reservoir, or suck fluid through the pump by suction action from the patient. The safety valve may be actuated by a separate actuator, or via a pressure differential established by the pump. An example of a pump-actuated active safety valve is disclosed in PCT/EP2006/060277 which is hereby incorporated by reference. The pump may be a reciprocating pump, such as a membrane pump or a piston pump.

Fig. 2 shows an embodiment of a drug infusion system 700, in which the functions of a check valve and a safety valve have been combined into an active valve in the form of one of the inlet valve 730 and outlet valve 750 in accordance with an aspect of the present invention. The other one of the valves 730, 750 is a passive check valve. Otherwise the pump assembly comprises the same components as in the fig. 1 embodiment. The passive check valve is controlled by the pressure difference across the valve, whereas the active valve is sequentially controlled with the pumping unit in such a way that it enables a forward flow of fluid through the drug infusion system.

With reference to figs. 3A-3C different embodiments for actuation and control means for the active valve will be described. More specifically, fig. 3A shows a pump assembly comprising a displacement pump 110 having a pump cavity 115, a pump membrane 114 and an actuator 113, a drug reservoir 120 connected to the pump cavity via an active inlet valve 130, and an outlet reservoir 140 (representing a patient) connected to the pump cavity via a passive outlet check valve 150. Via a conduit 117 the active valve is controlled directly by suction pressure generated by the pump. As appears, this will result in a slight delay in the opening of the inlet valve as the pump first has to generate the suction pressure. The actuator may be driven and controlled by any suitable means.

Fig. 3B shows a pump assembly of the same general design as the embodiment of fig. 3A with the addition of a controller 260, the controller being adapted to control the actuator 213

and, via the active valve 219, the flow of fluid in the conduit 218 between the pump cavity and the active inlet valve 230.

Fig. 3C shows a pump assembly of the same general design as the embodiment of fig. 3B, however, both the pump actuator 313 the active inlet valve 330 are directly controlled by the controller 360 via the valve actuator 331. The assembly further comprises pressure sensors 361, 362 on the inlet respectively the outlet side, the sensors serving as detecting means for detecting an elevated pressure condition in the inlet or a decreased pressure in the outlet conduit, the controller being adapted to close the active valve in response to the detection of the elevated or decreased pressure. In this way an undesired flow of fluid through the pump can be prevented during the normal open-cycle of the valve.

With reference to figs. 4-6 different designs of active micro valves will be described and characterized. As discussed above, an often used valve is a passive check valve, but in accordance with the present invention, the use of an active valve is investigated, as they have some interesting features with respect to safety, as they can independently control flow. One way of identifying active valves is by their stable modes, i.e., the mode they enter when power is off. The modes are, normally closed, normally open or bi-stable. An additional way of identifying valves would be by the way they operate. In the following three types of such valves have been categorized as gate valves, pinch valves, and active-material valves.

Figs. 4A and 4B show a gate valve in an open respectively a closed position. The gate valve 401 slides across the conduit 402 and blocks the flow. A gate valve can also be e.g. a turning valve, where the through going bore in a rod or a ball is parallel or transverse to the direction of the flow. The valve can be designed to be self sealing. A detailed description of a turning rod gate valve can be found in [7] which is hereby incorporated by reference. Figs. 5A and 5B show a pinch valve in an open respectively a closed position. When a pressure is applied by a pinch member 501 on the conduit wall 503, flow in the conduit 502 is pinched off. Such a valve is not self sealing, as a large fluid pressure requires a large external force to seal the channel. Figs. 6A and 6B show an active material valve in an open respectively a closed position. The flow conduit 602 contains an active material 601, which in an activated state 603 block the channel, when it is exerted to a field. It could for example be a fluid containing magnetic particles, which is effected by a magnetic field. The active material valve is not self sealing. According to this categorization the only self sealing valve is the gate valve, which is a highly desirable feature, as it does not require more energy to seal.

Various types of safety valve actuators may be incorporated in the drug infusion device of the present invention, e.g. those disclosed in [Ref. 5]. Thus, as examples, the following types of actuators are applicable: electromagnetic, electrostatic, thermo-mechanical, phase change, piezoelectric, shape memory alloy (SMA), magneto-strictive, electro-rheological, electro-hydrodynamic, and diamagnetism (Meissner effect) actuators. An additional suitable valve is the one described by Papavasilliou, Liepmann and Pisano [Ref. 6].

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

In the following a system suitable to be used in combination with the present invention will be described, the system comprising a pump unit, and a patch unit adapted to be used in combination with the pump unit.

Firstly, with reference to figs. 7-9 an embodiment of a medical device 800 for drug delivery will be described focusing primarily on the directly user-oriented features during application of the device to a skin surface. The patch unit 802 comprises a transcutaneous device in the form of a hollow infusion device, e.g. a needle or soft cannula, however, the needle or cannula may be replaced with any desirable transcutaneous device suitable for delivery of a fluid drug or for sensing a body parameter. For example, applicant's PCT/EP2006/050410, hereby incorporated by reference, discloses an alternative configuration in which the patch unit comprises a soft cannula.

More specifically, fig. 7 shows a perspective view of medical device in the form of a modular skin-mountable drug delivery device 800 comprising a patch unit 802 and a pump unit 805 (as the pump unit comprises a reservoir it may also be termed a reservoir unit). When supplied to the user each of the units are preferably enclosed in its own sealed package (not shown). The embodiment shown in fig. 7 comprises a patch unit provided with an insertable transcutaneous device, e.g. needle, cannula or sensor. In case an actual embodiment requires the patch unit to be mounted on the skin and the transcutaneous device inserted be-

fore a pump or other unit can be attached, it follows that the method of use would be adopted correspondingly.

The patch unit comprises a flexible patch portion 810 with a lower adhesive mounting surface 812 adapted for application to the skin of a user, and a housing portion 820 in which a transcutaneous device (not shown) is arranged. The transcutaneous device comprises a pointed distal end adapted to penetrate the skin of a user, and is adapted to be arranged in fluid communication with the pump unit. In the shown embodiment the pointed end of the transcutaneous device is moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface. The transcutaneous device may also be moveable between the extended position in which the distal end projects relative to the mounting surface, and a retracted position in which the distal end is retracted relative to the mounting surface.

The patch unit further comprises user-gripable actuation means in the form of a first strip-member 821 for moving the transcutaneous device between the initial and the second position when the actuation means is actuated, and a user-gripable second strip-member 822 for removing the patch from the skin surface. The second strip may also me used to move the distal end of the transcutaneous device between the extended and the retracted position. The housing further comprises user-actuatable male coupling means 831 in the form of a pair of resiliently arranged hook members adapted to cooperate with corresponding female coupling means on the pump unit, this allowing the pump unit to be releasable secured to the patch unit in the situation of use. A flexible ridge formed support member 813 extends from the housing and is attached to the upper surface 811 of the patch. The adhesive surface is supplied to the user with a peelable protective sheet.

The pump unit 805 comprises a pre-filled reservoir containing a liquid drug formulation (e.g. insulin) and an expelling assembly for expelling the drug from the reservoir through the needle in a situation of use. The reservoir unit has a generally flat lower surface adapted to be mounted onto the upper surface of the patch portion, and comprises a protruding portion 850 adapted to be received in a corresponding cavity of the housing portion 820 as well as female coupling means 851 adapted to engage the corresponding hook members 831 on the needle unit. The protruding portion provides the interface between the two units and com-

prises a pump outlet and contact means (not shown) allowing the pump to detect that it has been assembled with the patch.

In a situation of use the user assembles the two units which are then mounted on a skin surface where after the transcutaneous device is inserted and the pump is ready to operate. Operation may start automatically as the transcutaneous device is inserted, or the pump may be started via the remote unit, see below. Before the pump unit is mounted to the patch unit, the user will normally have paired the pump unit with the remote unit, see below. In an alternative situation of use the user may first mount the patch unit to a skin surface and insert the transcutaneous device, after which the pump unit is mounted to the patch unit.

After the assembled device has been left in place for the recommended period of time for use of the patch unit (e.g. 48 hours) – or in case the reservoir runs empty or for other reasons - it is removed from the skin by gripping and pulling the retraction strip 822 which may also lead to retraction of the transcutaneous device. The pump unit may be removed from the patch unit before or after the patch unit is removed from the skin. Thereafter the pump unit can be used again with fresh patch units until it has been emptied or the patch has to be changed again.

Fig. 10 shows the pump unit with an upper portion of the housing removed. The pump unit comprises a reservoir 560 and an expelling assembly comprising a pump assembly 500 as well as processor means 580 and a coil actuator 581 for control and actuation thereof. The pump assembly comprises an outlet 522 for connection to a transcutaneous access device and an opening 523 allowing a fluid connector arranged in the pump assembly to be actuated and thereby connect the pump assembly with the reservoir. The reservoir 560 is in the form of prefilled, flexible and collapsible pouch comprising a needle-penetratable septum adapted to be arranged in fluid communication with the pump assembly. The lower portion of the housing comprises a transparent area (not seen) allowing a user to inspect a portion of the reservoir. The shown pump assembly is a mechanically actuated membrane pump, however, the reservoir and expelling means may be of any suitable configuration.

The processor means comprises a PCB or flex-print to which are connected a microprocessor 583 for controlling, among other, the pump actuation, contacts (i.e. sensors) 588, 589 cooperating with corresponding contact actuators on the patch unit or the remote unit (see below), signal generating means 585 for generating an audible and/or tactile signal, a display

(if provided), a memory, a transmitter and a receiver. An energy source 586 provides energy. The contacts may be protected by membranes which may be formed by flexible portions of the housing.

With reference to figs. 7-10 a modular system comprising a pump unit and a patch unit has been described, however, the system may also be provided as a unitary unit.

In fig. 11A is shown an alternative embodiment of a medical device 1000 of the type shown in fig. 7, comprising a cannula unit 1010 and a thereto mountable pump (or reservoir) unit 1050, however, instead of a needle insertion mechanism as in the fig. 7 embodiment, a cannula inserter mechanism as disclosed in PCT application EP2006/050410 is used. In the shown embodiment the cannula unit comprises a housing 1015 with a shaft into which a portion 1051 of the pump unit is inserted. The shaft has a lid portion 1011 with an opening 1012, the free end of the lid forming a flexible latch member 1013 with a lower protrusion (not shown) adapted to engage a corresponding depression 1052 in the pump unit, whereby a snap-action coupling is provided when the pump unit is inserted into the shaft of the cannula unit. Also a vent opening 1054 can be seen. The housing 1015 is provided with a pair of opposed legs 1018 and is mounted on top of a flexible sheet member 1019 with a lower adhesive surface 1020 serving as a mounting surface, the sheet member comprising an opening 1016 for the cannula 1017.

As appears, from the housing of the cannula unit a cannula extends at an inclined angle, the cannula being arranged in such a way that its insertion site through a skin surface can be inspected (in the figure the full cannula can be seen), e.g. just after insertion. In the shown embodiment the opening in the lid provides improved inspectability of the insertion site. When the pump unit is connected to the cannula unit it fully covers and protects the cannula and the insertion site from influences from the outside, e.g. water, dirt and mechanical forces (see fig. 11B), however, as the pump unit is detachable connected to the cannula unit, it can be released (by lifting the latch member) and withdrawn fully or partly from the cannula unit, this allowing the insertion site to be inspected at any desired point of time. By this arrangement a drug delivery device is provided which has a transcutaneous device, e.g. a soft cannula as shown, which is very well protected during normal use, however, which by fully or partly detachment of the pump unit can be inspected as desired. Indeed, a given device may be formed in such a way that the insertion site can also be inspected, at least to a certain degree, during attachment of the pump, e.g. by corresponding openings or transparent ar-

eas, however, the attached pump provides a high degree of protection during use irrespective of the insertion site being fully or partly occluded for inspection during attachment of the pump.

Figs. 12A and 12B show a valve 900 with self-sealing capability due to use of an incompressible material. The valve comprises an inlet 901 and an outlet 902, a valve body 920 arranged in a rigid housing 930 and being made from a flexible, incompressible material. A valve member 910 in the form of a cylindrical rod comprising a through-going opening 911 is rotatably arranged in a corresponding cylindrical bore in the valve body between an open position in which a flow pathway is provided between the inlet and the outlet, and a closed position in which the flow pathway between the inlet and the outlet is blocked. A seal is formed between the contacting surfaces of the valve member and the flexible, incompressible material of the valve body. When the valve is in its closed position and the pressure increases on either the inlet or outlet side of the valve member, the flexible, incompressible material on the pressurized side of the valve member is displaced inside the housing towards the opposed side of the valve member, thereby creating a pressure seal between the valve member and the displaced material (see fig. 12B). In the shown embodiment the flexible, incompressible material forms a portion of the inlet and the outlet, whereby pressure in these conduits can be directly transferred to the flexible, incompressible material.

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

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CLAIMS

1. A pump assembly (700), comprising:
- a displacement pump (710),
- an inlet valve (730) allowing a flow of fluid into the displacement pump,
- an outlet valve (750) allowing a flow of fluid from the displacement pump,
- wherein either the inlet or the outlet valve is a passive valve controlled by a pressure differential across the valve generated by the displacement pump, and the other of the inlet and the outlet valve is an active valve controllable by actuation means.

2. A pump assembly as in claim 1, wherein the active valve is closed when not actuated.

3. A pump assembly as in claim 1, wherein the active valve can be positioned in either a closed or open position.

4. A pump assembly as in any of claims 1-3, wherein the active valve (230) is activated by fluid pressure generated by the displacement pump, the fluid pressure to the active valve being controllable by actuation means (219, 260).

5. A pump assembly (300) as in any of claims 1-4, further comprising:
- a controller (360),
- a pump actuator (313) for actuating the displacement pump,
- a valve actuator (331),
- wherein the controller is adapted to actuate the pump actuator respectively the valve actuation means to provide a flow of fluid through the displacement pump.

6. A pump assembly as in any of claims 1-5, further comprising an inlet conduit associated with the inlet valve and an outlet conduit associated with the outlet valve.

7. A pump assembly as in claim 6, further comprising:
- detecting means (361, 362) for detecting an elevated pressure condition in the inlet or a decreased pressure in the outlet conduit,
- wherein the controller (360) is adapted to close the active valve in response to the detection of the elevated or decreased pressure.

8. A pump assembly as in any of the previous claims, further comprising a flexible reservoir (560) containing a fluid drug in an interior thereof, the reservoir being in fluid communication with or adapted to be arranged in fluid communication with the inlet valve.

9. A pump assembly as in any of the previous claims, further comprising a transcutaneous device (1017) adapted to be inserted through the skin of a subject, the transcutaneous device being arranged or adapted to be arranged in fluid communication with the outlet valve.

10. A medical assembly comprising a pump assembly (805, 1050) as in any of claims 1-8, further comprising a transcutaneous device unit (802, 1010) comprising:

- a transcutaneous device (1017) adapted to be inserted through the skin of a subject,
- a mounting surface (812, 1020) adapted for application to the skin of a subject,
- wherein the transcutaneous device unit and the pump assembly are adapted to be mounted to each other in a situation of use, and
- wherein the transcutaneous device is adapted to be arranged in fluid communication with the outlet valve.

11. A method for operating a pump assembly, the pump assembly comprising:

- a displacement pump,
- an active inlet valve allowing a flow of fluid into the displacement pump, the active valve being controllable by external means between a closed and an open state, and
- a passive outlet valve allowing a flow of fluid from the displacement pump,

the method comprising the steps of:

- opening the active valve,
- activating the displacement pump to perform a suction stroke,
- closing the active valve, and
- activating the displacement pump to perform an expelling stroke, the displacement pump thereby creating a pressure differential across the passive outlet valve, thereby opening the outlet valve.

12. A method for operating a pump assembly, the pump assembly comprising:

- a displacement pump,
- a passive inlet valve allowing a flow of fluid into the displacement pump, and

- an active outlet valve allowing a flow of fluid from the displacement pump, the active valve being controllable by external means between a closed and an open state,

the method comprising the steps of:

- activating the displacement pump to perform a suction stroke, the displacement pump thereby creating a pressure differential across the passive inlet valve, thereby opening the inlet valve,
- opening the active valve,
- activating the displacement pump to perform an expelling stroke, and
- closing the active valve.

13. A pump assembly as in any of the previous claims, wherein at least one valve (900) comprises:

- an inlet (901) and an outlet (902),
- a valve body (920) comprising a flexible, incompressible material,
- a valve member (910) comprising a through-going opening (911) and being moveable between an open position in which a flow pathway is provided between the inlet and the outlet, and a closed position in which the flow pathway between the inlet and the outlet is blocked, a seal being formed between the valve member and the flexible, incompressible material,
- wherein in a closed position of the valve a pressure increase on either the inlet or outlet side of the valve member displaces flexible, incompressible material on the pressurized side of the valve member to an opposed side of the valve member, thereby creating a pressure seal between the valve member and the displaced material.

14. A pump assembly as in claim 13, wherein at least a portion of the flexible, incompressible material is enclosed within a surrounding rigid housing ensuring that the incompressible material is displaced from the pressurized side of the valve to the opposed side.

*****

Fig. 1

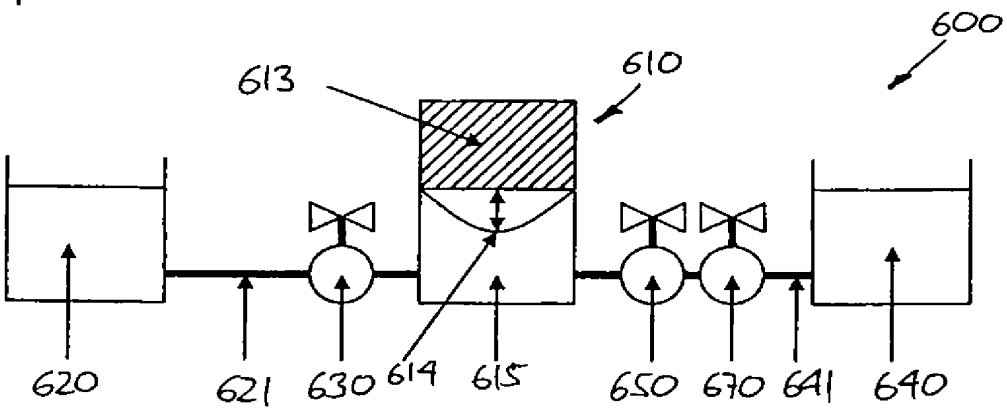
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Fig. 2

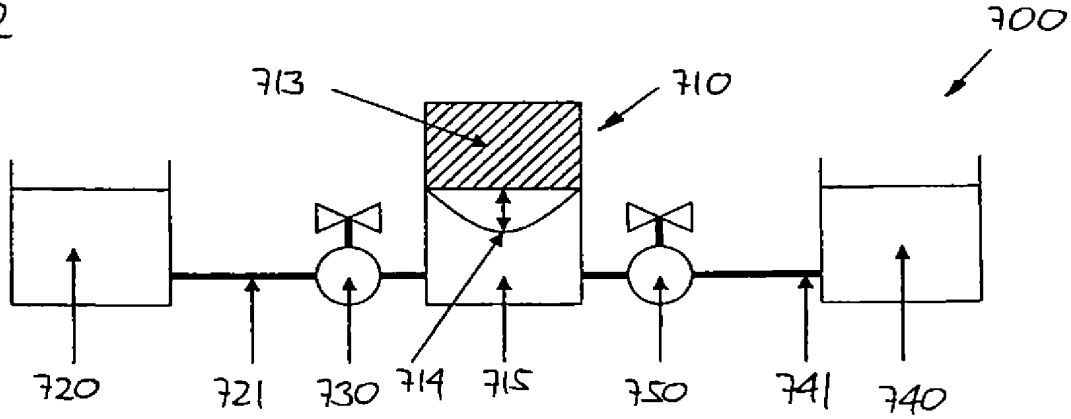
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Fig. 3A

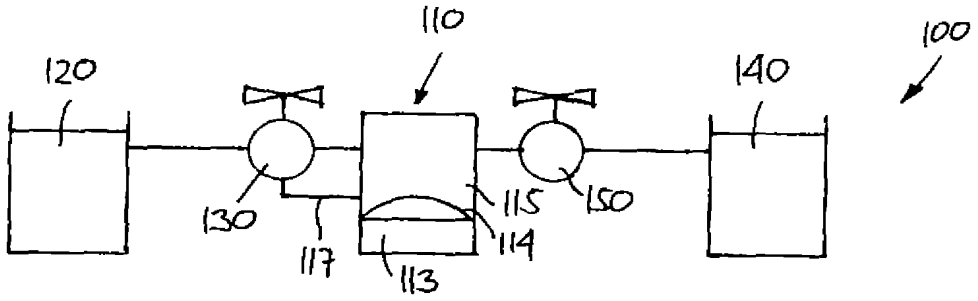

Fig. 3B

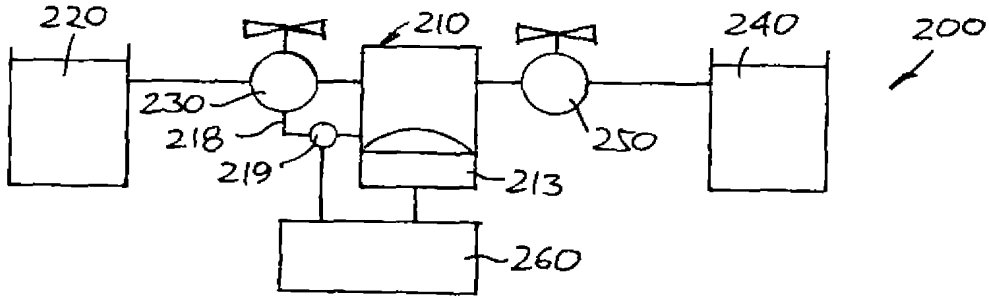

Fig. 3C

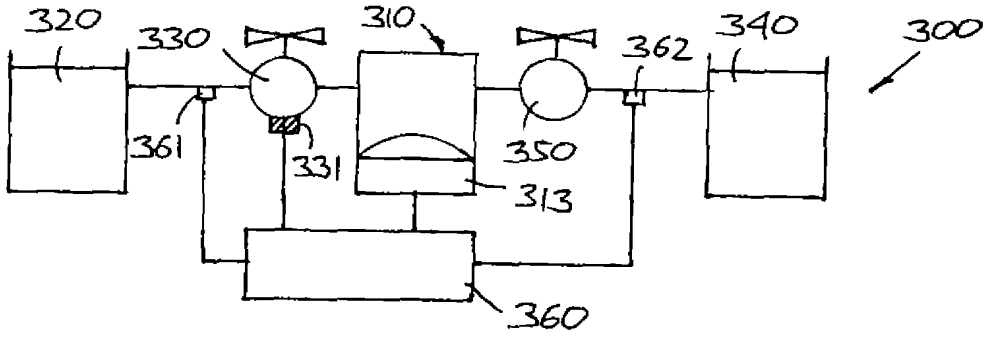

Fig. 4A

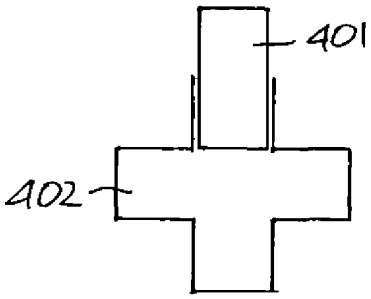

Fig. 4B

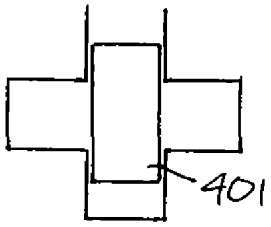

Fig. 5A

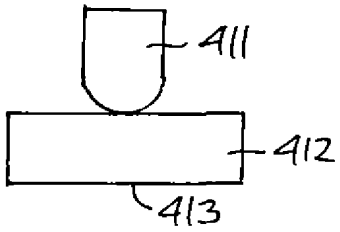

Fig. 5B

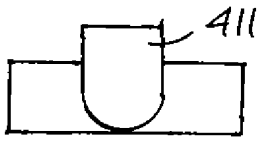

Fig. 6A

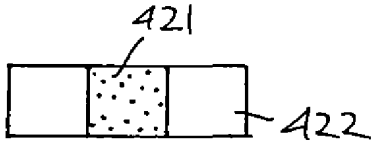

Fig. 6B

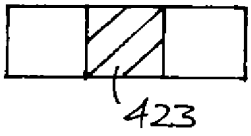

Fig. 7

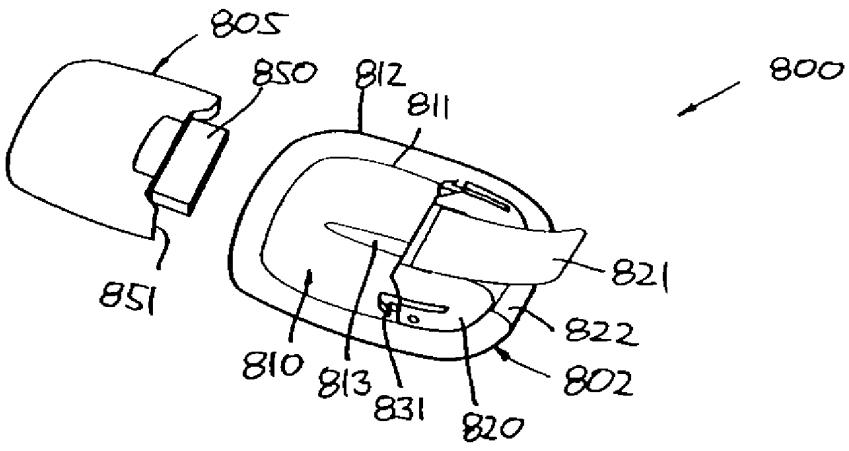

Fig. 8

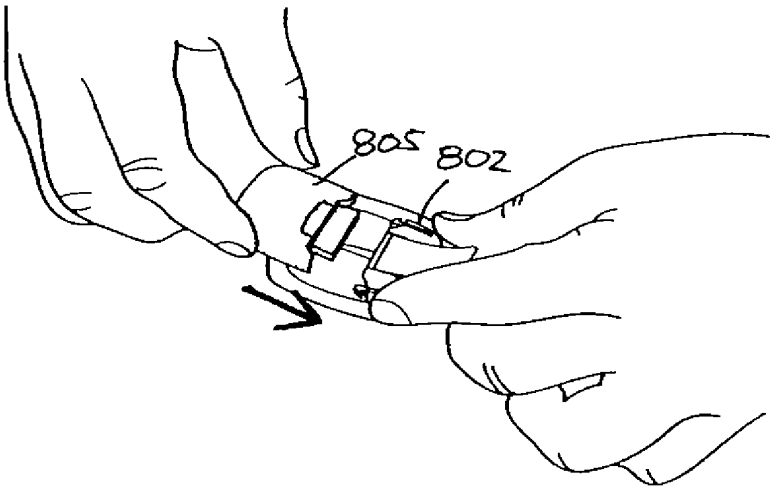

Fig. 9

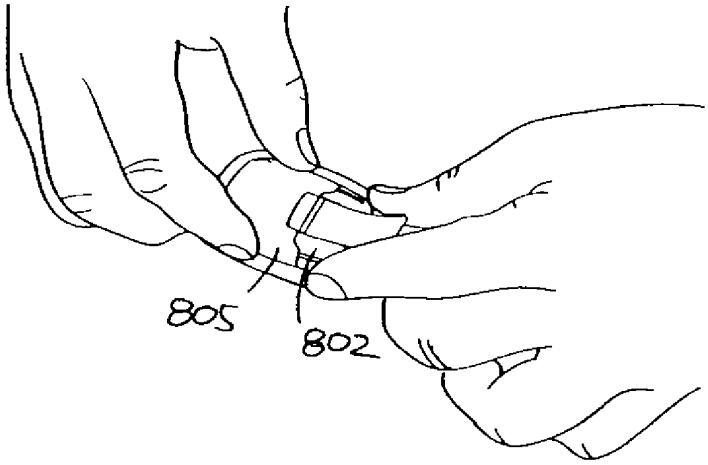

Fig. 10

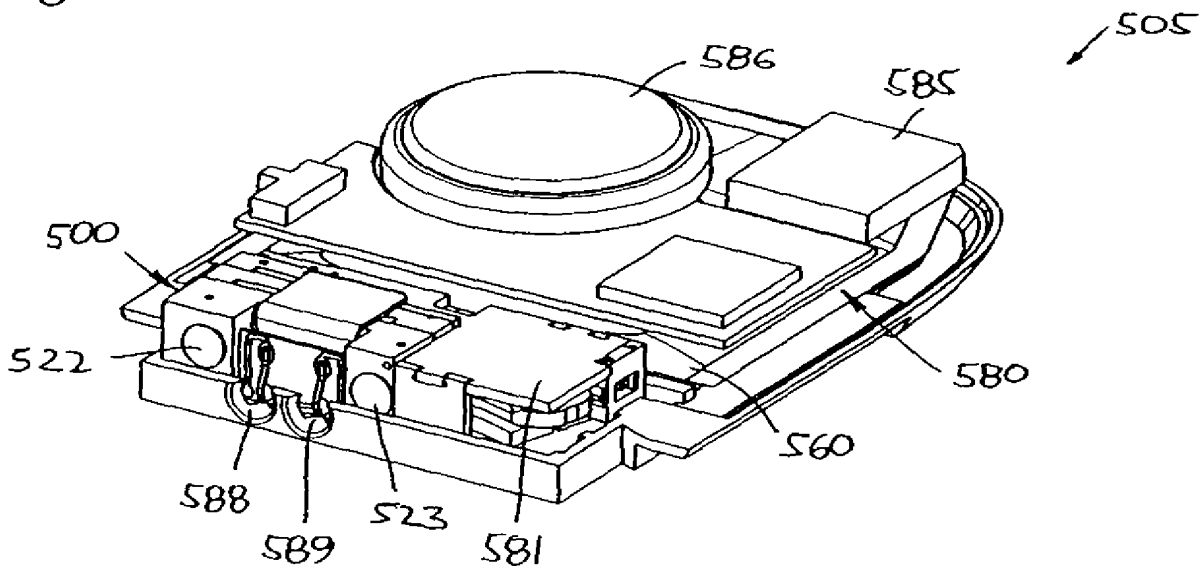

Fig. 12A

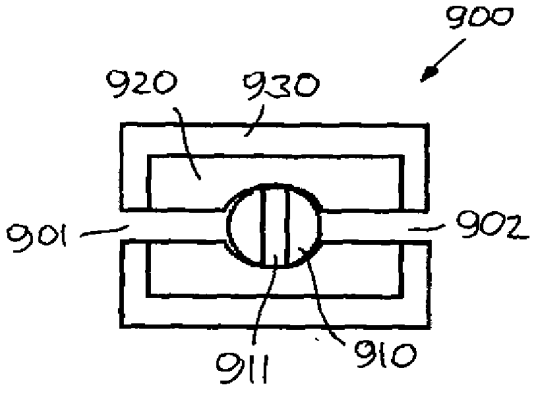

Fig. 12B

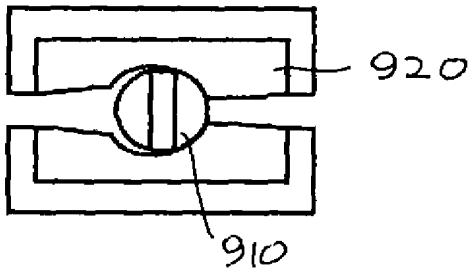

Fig. 11A

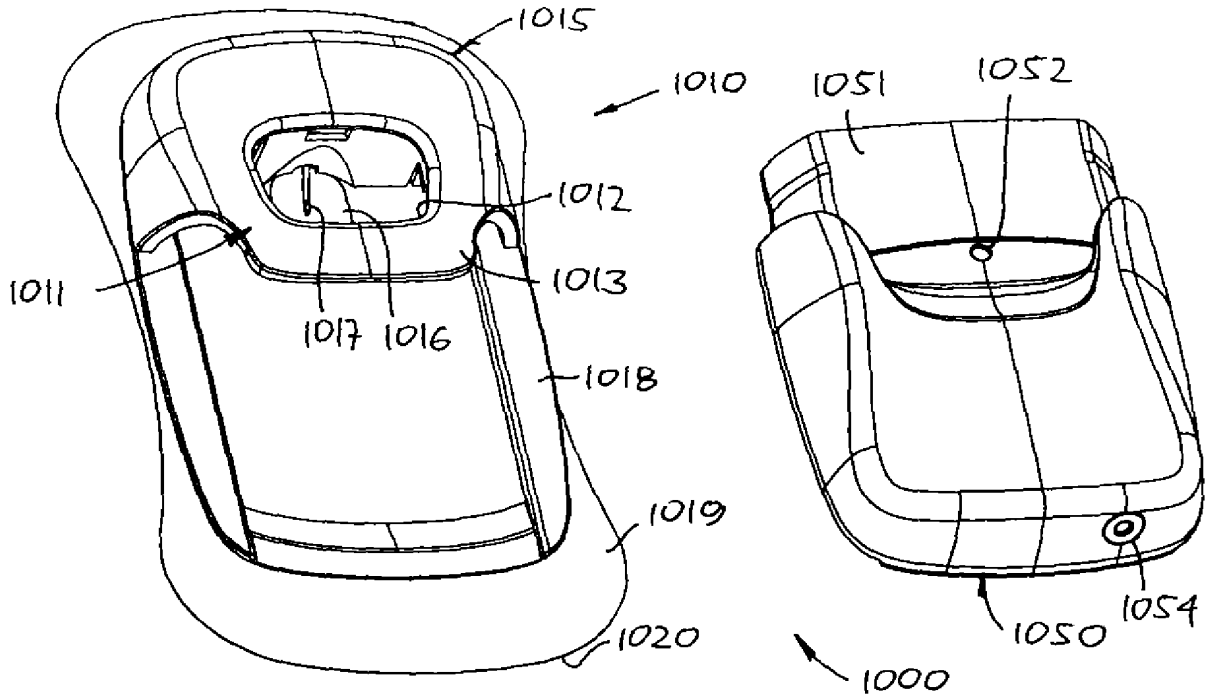

Fig. 11B